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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/915,411	07/25/2001	Richard Horuk	51882AUSM1	7050

7590 10/03/2003

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EXAMINER
DESAI, ANAND U

ART UNIT	PAPER NUMBER
1653	

DATE MAILED: 10/03/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/915,411	HORUK, RICHARD	
	Examiner	Art Unit	
	Anand U Desai	1653	

-- Th MAILING DATE of this communication appears on the cover she t with the correspond nc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *30 September 2003* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-17* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-17* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☒ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *1-2* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

Specification

1. The use of the trademark ACCU-PAQUE (example 1, page 18, line 21) has been noted in this application. It should be capitalized wherever it appears and be accompanied by the generic terminology.

Although the use of trademarks is permissible in patent applications, the proprietary nature of the marks should be respected and every effort made to prevent their use in any manner which might adversely affect their validity as trademarks.

Claim Rejections - 35 USC § 112

2. The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 6-17 are rejected under 35 U.S.C. 112, second paragraph, as being incomplete for omitting essential steps, such omission amounting to a gap between the steps. See MPEP § 2172.01. The omitted steps are: Claims 6, and 12 do not describe a method of administering the pharmaceutical composition. Claim 7 depends from a rejected independent claim 6; Claim 8 depends from a rejected dependent claim 7; Claims 9-11 depend from a rejected dependent claim 8. Claim 13 depends from a rejected independent claim 12; Claim 14 and 15 depend from a rejected dependent claim 13; Claim 16 and 17 depend from a rejected dependent claim 15.

Claim Rejections - 35 USC § 103

3. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

4. Claims 1-17 are rejected under 35 U.S.C. 103(a) as being unpatentable over Gao et al. (J. Clin. Invest. 2000; 105(1):35-44) in view of Bauman et al. (U.S. Patent 6,207,665 Effective filing date=June 9,1998). Gao et al. teaches that cell infiltration and immune activation are suppressed in CCR1 -/- (knockout) mice treated with 10 mg/kg of cyclosporin A (See pg 39, Effects of low-dose CsA therapy on intragraft infiltrates). MHC class II-mismatched cardiac allografts from these mice were free of transplant arteriosclerosis and the mice permanently accepted the cardiac allograft (See pg 40, CCR1 -/- Mice permanently accept MHC class II-mismatched cardiac allografts). Gao et al. conclude that blocking CCR1-ligand interactions maybe useful for preventing acute and chronic organ rejection. Gao et al. does not teach non-peptide CCR1 receptor antagonist.

Bauman et al. teaches piperazine derivatives as CCR1 receptor antagonists (Column 155-156, Example 26, In vitro Assay). Note that in the Bauman Patent (U.S. Patent 6,207,665) claims 2-11 lists the receptor antagonist of instant U.S. application 09/915,411 claims 2-4, 8-10, and 13-15 (See column 164, lines 48-50, column 167, lines 50-61).

It would have been obvious to a person having ordinary skill in the art to administer the non-peptide CCR1 receptor antagonist of Bauman et al. with cyclosporin

A to treat heart transplantation rejection because Gao et al. teach the combination of CCR1 receptor elimination and cyclosporin A prevents cardiac allograft rejection and permanent acceptance of cardiac allograph tissue in vivo and suggests that blocking CCR1-ligand interaction and administering cyclosporin A will be useful for preventing heart transplant rejection in vivo (**Claims 1-17**).

September 30, 2003

KAREN COCHRANE CARLSON, PH.D
PRIMARY EXAMINER